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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 31671-176817

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Application Number	Filed
10/031,331	January 18, 2002

First Named Inventor: Akiyo YAMADA et al.

Art Unit	Examiner
1638	Medina A. Ibrahim

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒ attorney or agent of record. Registration number 36,830

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

C. A. Hobbs
Signature

Ann S. Hobbs, Ph.D.
Typed or printed name

202-344-4651
Telephone number

September 27, 2005
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 1 forms are submitted.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	
Akiyo YAMADA et al.	Art Unit: 1638
Appl'n No.: 10/031,331	Examiner: Medina Ahmed Ibrahim
Filed: January 18, 2002	Attorney Docket No.: 31671-176817
For: ENVIRONMENTAL STRESS TOLERANT GENE	

Customer No.
26694
PATENT TRADEMARK OFFICE

Pre-Appeal Brief Request for Review

Mail Stop: AF amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Advisory Action issued July 28, 2005, Applicants submit the following remarks.

Rejection under 35 USC § 112, first paragraph, for lack of enablement

Claims 64-66, 114-117, 121-122 and 125 stand rejected under 35 USC § 112, first paragraph, as not being enabled. In the Advisory Action, the Examiner maintains that the specification "does not support use of SEQ ID NO:39 encoding SEQ ID NO: 40 having salt tolerance activity in a transgenic plant." The Examiner states that the fact that SEQ ID NO:39 is isolated from a halophyte does not inherently imply that the sequence induces salt tolerance in a transgenic plant, and further that "[a]pplicant has not described a representative number of DNA having both the structural and functional properties of claim 66."

Applicants respectfully traverse. Independent claim 64 is limited to isolated DNA encoding a protein comprising the sequence set forth in SEQ ID NO:40, and having the activity of improving tolerance at least against salt stress. Independent claim 65 is limited to isolated DNA comprising the sequence of bases shown in SEQ ID NO:39, or its complementary sequence. Claim 66 is limited to an isolated DNA which hybridizes with the DNA according to claim 65 under stringent conditions that are recited in the claim, and encodes a protein having the activity of improving tolerance at least against salt stress. Claims 114-117 are limited to vectors, transformed host cells, and methods of producing protein utilizing the DNA compositions of claims 64-66. Claims 121, 122 and 125 are limited to plants comprising the DNA of claims 64-66. Thus, all of the claims under examination are limited to compositions comprising specific nucleic acid sequences that encode the protein of SEQ ID NO:40, sequences that are complementary thereto, or sequences that hybridize thereto under stringent conditions, and a method that uses the claimed compositions to produce a protein that improves environmental stress tolerance, e.g. salt tolerance.

Applicants have developed a method for screening for DNA sequences encoding proteins that confer tolerance to, *inter alia*, salt stress. The method uses strains of coliform bacteria in which the tolerance for salt is low in comparison to other coliform bacteria, so that the selection process reliably results in the selection of genes that are relevant to salt tolerance (see, e.g. page 5, first paragraph, of the specification). Applicants have demonstrated that DNA sequences identified by this screening method improve salt tolerance in yeast, plant cells and whole plants, by introducing the mang1 sequence, identified by this process, into these organisms and testing their salt tolerance under appropriate conditions. This is demonstrated in Examples 1 (preparation of cDNA library), 2 (determination of screening conditions for salt tolerance), 3 (screening relevant to salt tolerance in mangrove and other halophytes), 4 (effects of Mangrove cDNA in yeast), 5 (effects of Mangrove cDNA in cultured tobacco cells), and 6 (effects of Mangrove cDNA in plants). Figure 5 shows the effects of salt on plants that have been transformed with a DNA sequence identified by this method compared to control plants, and clearly demonstrates the efficacy of the method in identifying sequences that will confer salt

tolerance. Accordingly, it is respectfully submitted that persons of skill in the art would appreciate that other DNA sequences identified by the method, such as claimed sequences 39 and 40, will confer similar characteristics. It is noted that SEQ ID NO:39 is identified at page 33, line 14, of the specification, and SEQ ID NO:40 is identified at page 35, line 19 (Example 3) in connection with the screening method.

With regard to the Examiner's position that Applicant has not described a representative number of DNA having both the structural and functional properties of claim 66, it is noted that the claim is limited to sequences that are hybridized under specifically recited stringent conditions, and encode proteins that have the characteristic of inducing salt tolerance. It is respectfully submitted that persons of skill in the art will be able to identify such sequences without undue experimentation using the description provided by the specification and the general knowledge in the art. Such sequences can be identified by routine hybridization procedures under the recited conditions, and tested by transforming cells with the identified sequences and testing them for salt tolerance, as described in Examples 3-6.

For all of the above reasons, it is respectfully submitted that claims 64-66, 114-117, 121-122 and 125 meet the enablement requirements of 35 USC § 112, first paragraph. Withdrawal of the rejection is respectfully requested.

Furthermore, in the amendment filed December 16, 2004, which is incorporated herein by reference, applicants provided Reference Figure 1, showing that *E. coli* that is transformed with the DNA of SEQ ID NO:39 encoding the protein (Sj-PEAMT) shown by SEQ ID NO: 40 exhibits an improved salt tolerance compared to the control (*E. coli* transformed with pBluescript SK) in the presence of 450 mM NaCl, although there is no difference between the two types of *E. coli* regarding the improvement of salt tolerance in the presence of 86 mM NaCl. In addition, Applicants provided Reference Figure 2, demonstrating that *E. coli* that is transformed with the DNA of SEQ ID NO:39 encoding the protein (Sj-PEAMT) shown by SEQ ID NO: 40 produces greater amount of Glycine betaine (GB) than does the control (*E. coli* transformed with pBluescript SK) in the presence of 500 mM NaCl, although there is no difference between the two types of *E coli* regarding the GB amount produced in the presence of 86 mM NaCl. *E. coli*

accumulates GB by oxidizing choline (as occurs in plants). Sj-PEAMT is a necessary enzyme for producing choline, and it is presumed that *E. coli* transformed with Sj-PEAMT is accumulating choline. It is thought that GB contents under salt stress differ greatly due to the fact that a choline oxidizing enzyme held by *E. coli* itself inactivates under salt stress. This evidence demonstrates that SEQ ID NO: 39 confers salt tolerance on these cells as described and claimed. It is noted that the Examiner has not commented upon this evidence.

For these reasons, withdrawal of the enablement rejection under 35 USC § 112, first paragraph, is requested.

Rejection under 35 USC § 112, first paragraph, for lack of written description

Claims 64-66, 114-117, 121-122 and 125 stand rejected under 35 USC § 112, first paragraph, as failing to comply with the written description requirement for the reasons noted above. Applicants respectfully traverse.

As noted above, the specification sets forth a detailed description of how to identify sequences useful for conferring salt tolerance on cells and organisms, transform cells using such sequences, and obtain salt tolerant cells and plants. Detailed examples have been provided that allow identification of sequences useful for inducing salt tolerance. The method has been validated using mang1, identified by the method, to obtain a transformed plant that is salt tolerant, as demonstrated by Figure 5. SEQ ID NOS: 39 and 40 were identified and described in the specification (e.g. at pages 33 and 35) as being useful for these purposes. Methods well known in the art can be used to obtain sequences that are complementary to or that hybridize to SEQ ID NO:39 under stringent conditions, as recited in claims 65 and 66, as well as vectors and transformed cells. The methods set forth in detail in Examples 3-6 can be used to obtain cells and plants transformed by the claimed sequences. The Examiner has provided no evidence to doubt the assertions of Applicants that SEQ ID NOS: 39 and 40, or any of the claimed compositions and methods, would function as claimed. Accordingly, it is submitted that the present claims meet the written description requirements of 35 USC § 112, first paragraph.

For all of these reasons, it is respectfully submitted that the invention as currently claimed meets the written description requirements of 35 USC § 112, first paragraph. Reconsideration and withdrawal of the rejection is respectfully requested.

In conclusion, it is respectfully submitted that the pending claims meet both enablement and written description requirements of 35 USC § 112, first paragraph. Withdrawal of the rejections is respectfully requested.

Respectfully submitted,

Date: 9/27/05

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